UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,765	03/20/2007	Mahendra G. Dedhiya	MERZ 49 PCT US	1522

25666 7590 07/17/2009

THE FIRM OF HUESCHEN AND SAGE
SEVENTH FLOOR, KALAMAZOO BUILDING
107 WEST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER
THOMAS, TIMOTHY P

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
07/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/578,765	**Applicant(s)** DEDHIYA ET AL.	
	Examiner TIMOTHY P. THOMAS	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-7,13-16,26,39-41 and 44*.
   Claim(s) withdrawn from consideration: *17-25 and 27-32*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 3/2/2009
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/Timothy P Thomas/
Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because: The rejections of record are maintained for the reasons of record:

Claims 1-3, 6-7, 14-16 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Parsons et al. (WO 01/98253 A2; 2001 Dec)..

Applicant argues that according to MPEP 2112, in order to rely on a theory of inherency the Office must provide a basis in fact and/or technical reasongin to reasonably support that the inherent characteristic necessarily flows from the teachings of the applied prior art; that the fact at a certain result or characteristic may occur or be present in the prior art is not enough to establish the inherency of that result or characteristic. It is noted that such a basis has been provided on the record. Each component of an injectable solution is suitable for oral ingestion. Therefore, the solution formed the combination of orally suitable ingredients would also be suitable "for oral administration", irrespective of the intended use taught in the reference.

In response to applicant's argument that Parsons discusses oral compositions at a different location from solutions for injection, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. This is the case for the intended use limitation, "for oral administration". As present on the record all ingredients in the injection solutions would be suitable for oral administration. The structural components present do not dictate how the composition is used, whether for oral or injection administration.

Additionally, applicant has not met the burden to demonstrate that the injection solutions are somehow not suitable for oral administration. Therefore, the rejection is maintained.

Claims 1, 4-5 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (WO 01/98253 A2; 2001 Dec).

Claims 1, 13, 26, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (WO 01/98253 A2; 2001 Dec) and Gupta et al. (US 2005/0014743 A1; priority 2003 May).

Applicant argues the Office has not provided an adaquate basis demonstrating the instant preservative free neramexane compositions for oral administration are inherent in the Parsons disclosure of a solution for injection; therefore, the compositions are not taught or suggested by the disclosure of Parsons, either alone or in combination with the Gupta disclosure. This is not persuasive for ther reasons discussed above.

Applicant further argues that the data in the specification may be extrapolated to provide support for the compositions comprising further excipients and that the Office has provided no basis for its allegation that additional excipients would be expected to alter the antimicrobial properties of the instant preservative free neramexane compositions. This is not persuasive. MPEP 2145 indicates such an extrapolation may be made if a skilled artisan could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof. In the limit of lower concentration, the data provided clearly exemplifies that the "unexpected result is not extended to 0.5 mg/mL, which does not show the same antimicrobial activity, where growth of two microorganisms was found. Therefore, with respect to the concentrations of the claims, amounts less than 5 mg/mL do not present such evidence. With respect to additional excipients, the claims are open to any components; some components, such as the addition of ethanol or higher salt concentrations, discussed on the record, would be expected to provide the antimicrobial activity; other components that provide a food source for microorganisms would be expected to increase growth of microorganisms. Such considerations do not allow the extrapolation to provide support for the entire claim scope, for even the most limited claims. Therefore, the limited results of the disclosure are not commensurate in scope with the claims.

Applicant continues to argue the Restriction Requirement is improper because the claims involve unity of invention. This is not persuasive; all of the claims under examination have one or more prior art rejections that have been maintained, demonstrating that unity of invention is lacking. No rejoinder of withdrawn claims is made at this time. Indeed the responsibility of the Final Office Action at Item #5 indicated the non-elected claims were required to be canceled in a complete reply to the final rejection, which has not been done.

The IDS reference discussed by applicant has been considered; a copy is attached